Recombinant DNA Advisory Committee Submission
BB IND 7550
Protocol Number TG1031.03
Protocol Title: Phase I/II Trial of Antigen-Specific Immunotherapy in MUC1 Positive Patients with Adenocarcinoma of the Prostate Using Vaccinia Virus-MUC1-IL2

Scientific Abstract

A phase I/II open label, dose-escalating, single center study comparing 5 x 10^5, 5 x 10^6, and 5 x 10^7 pfu dose levels of Vaccinia-Virus-MUC1-IL2 (VV-MUC1-IL2) given by intramuscular injection every four (4) weeks. Two groups of patients will be enrolled into this study; (1)metastatic adenocarcinoma of the prostate with doubling of the PSA over the previous 6 months or (2)status post treatment of primary prostate cancer treated with either surgery or radiation therapy and a documented rising PSA of at least 25% over the preceding 30 to 60 days. Patients will receive multiple courses of treatment as tolerated and will be followed until there is evidence of progressive disease. In the phase I portion of the study, cohorts of 3 patients will be enrolled into each progressive dose level. The next dose level will not be initiated until all three patients have received an injection at the previous dose and been observed for at least 28 days. The objective of this phase of the study is to determine the maximum tolerated and biologically active dose. Dose escalation will continue to the 5 x10^7 dose or until Grade III or IV toxicity, whichever occurs first. The phase II portion of this study will be initiated after the completion of phase I and will continue enrollment to 14 patients into each of the two stratified groups. The objectives of phase II are to determine the rate of objective tumor response, duration of disease control, and assess the safety and tolerance of repeated VV-MUC1-IL2 dosing. Assessment criteria will include the overall response rate (number of patients with an objective response divided by the total number of patients treated); duration of disease control (time to disease progression will be used to calculate a Kaplan Meier life table curve), and the incidence of adverse events to assess safety. The study is designed to detect a 20% objective response rate in each of the patient cohorts based on changes in the PSA.